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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/330,215	06/11/99	PORTA	R P8907-9014
			EXAMINER

HM22/0406  
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KISHORE, G	PAPER NUMBER
ART UNIT	

1615

DATE MAILED: 04/06/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1-16-01

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s); or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-12 & 19-22 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 1-12 & 19-22 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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### **DETAILED ACTION**

**The request for the extension of time and amendment filed on 1-16-01 are acknowledged.**

**Claims included in the prosecution are 1-12 and 19-22.**

#### ***Claim Rejections - 35 U.S.C. § 103***

1. **The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

2. **Claims 1-12 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's statements of prior art in combination with Litzinger (BBA, 1996) of record by itself or in further combination with Maccarone (BBRC, 1992), Eastman (Human Gene Therapy, 1997) individually or in combination.**

**Applicant indicates on pages 3-7 of the specification that instant polynucleotides are known for their function.**

**Litzinger while disclosing formulations containing cationic liposomes and their complexes with polynucleotides teaches that oligonucleotides have the inability to efficiently traverse through cellular membranes and hence complexation with cationic liposomes (note the abstract and page 140).**

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**Maccarone teaches that DNA when complexed with cationic liposomes are able to transfect protoplasts (note the abstract).**

**Similarly, Eastman teaches that the complex prepared by the addition of cationic liposomes and DNA has an efficient transfection ability (note the abstract and Materials and methods).**

**The use of cationic liposomes for the delivery of art known polynucleotides would have been obvious to one of ordinary skill in the art in view of Litzinger's teachings that oligonucleotides do not have the ability to cross cellular membrane, but are able to efficiently transfect when complexed with cationic liposomes as also shown by Maccarone and Eastman.**

**Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant points out to page 27 of the specification and argue that the results indicate the stability of the complex containing cationic lipid and the polydeoxynucleotides obtained by depolymerization compared to regular liposomes. These arguments are not found to be persuasive since first of all, claims are not commensurate in scope with regard to the molecular weight of the polydeoxynucleotides (page 27 reports 16,000 molecular weight compound whereas the claims are drawn to 7000-60,000) and also with respect to the generic cationic lipid.. Irrespective of this, stability of the polynucleotides in a complex form with a cationic lipid is to be expected and not unexpected since the reference of Zelphati (J. Of Liposome Research) submitted by applicant himself shows enhancement of**

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**the stability of oligonucleotides by cationic liposomes (note the abstract). Based on the stability, applicant also argues that the prior art does not teach this stability. It is the examiner's position that the prior art clearly points out the rationale for using cationic liposomal complexes for the delivery of the nucleotides and nucleic acids, that is, 'efficient transfer' of these molecules and irrespective of their molecular weights one would expect at least similar transfer. The motivation to combine need not be the same as applicant's and as pointed out above, stability as claimed by applicant as 'unexpected' is to be expected based on Zelphati. The rejection is maintained.**

- 3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

**A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the**

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**advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.**

- 4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

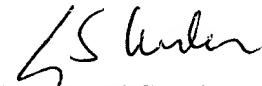
**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility**

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that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**April 2, 2001**